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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,184	06/07/2001	Tadaoki Takii	010493	7678

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EXAMINER
GORDON, BRIAN R

ART UNIT	PAPER NUMBER
1743	3

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,184	TAKII ET AL.	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim1 is rejected under 35 U.S.C. 102(e) as being anticipated by Tajima US 6,455,325.

Tajima discloses a processing method making use of a pipette device which sucks a liquid containing a target high molecular substance from inside of a vessel through a chip detachably set on a sucking port or a discharging port of a liquid sucking/discharging line and transfers this liquid or target high molecular substance to the next target processing position for the purpose to execute such works as quantifying, separating, taking out, pipetting, clarifying condensing, and diluting a liquid or a target high molecular substance contained in a liquid and also such works as

extracting, recovering, and isolating the target high molecular substance by means of sucking and discharging a liquid with a pipette device and controls by a magnetic body over magnetic particles and/or a filter combined according to the necessity, and the chip can isolate the target high molecular substance by having the substance attracted onto magnetic particles or with a filter set on each chip.

The pipette nozzle P is connected directly or with a certain but small range to a cylinder which can strictly control a sucking/discharging rate with a servo motor or a pulse motor and unitized therewith.

A nozzle **unit J supporting** this pipette nozzle P comprises, as shown in FIG. 2, a vertical movement guide body 1 movably supported in the XY direction (horizontal direction), a holder 2 connected with the vertical movement guide body 1 and moving in the vertical direction, a supporting body 3 extending in the horizontal direction from this holder 2, the pipette nozzle P penetrating this supporting body 3 in the vertical direction and supported thereby, a **spring** 4 provided in the supporting body 3 and **energizing the pipette nozzle P in the downward direction** in its normal state, and a hook bodies 6, 6 rotatably supported on the opposite side to a lower projecting section 5 of the supporting body 3. It should be noted that the sign Z in the figure indicates a sensor controlling a downward moving rate of the pipette nozzle P.

The nozzle unit having the configuration as described above is built so that it can move in the **XYZ directions** (in the horizontal direction and in the vertical direction) with the chips T.sub.1, T.sub.2, T.sub.3 engaged in a tip section of the pipette nozzle P supported by this nozzle unit J, and this engagement is maintained because the hook

bodies 6, 6 locks a flange 8 Of the chips T.sub.1, T.sub.2, and T.sub.3 in the state in which the hook body holds and embraces the chips.

4. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Tyberg et al. Us 6,270,726.

Tyberg discloses a pipetting station having a bottom sensing device is provided in conjunction with one of any known liquid level sensing devices. The bottom sensing device includes a pipetting probe **spring** mounted to a pipetting arm of the pipetting station. The bottom sensing device also includes a sensor for determining when a pipetting tip of the pipetting probe is in contact with a bottom of a tube. The bottom sensing device permits the pipetting probe to measure an exact volume of fluid in the tube by allowing the pipetting tip (suction nozzle) to be lowered to the bottom of the tube beyond the sensed fluid level.

The pipetting station 24 (moving means) includes the pipetting arm 32 (support means) that moves in the direction of arrow 42, and a pipetting probe 34 **spring** mounted to the pipetting arm 32 of the pipetting station 24. The pipetting probe 34 includes a pipetting tip 36 having a capacitive level sensor as described with reference to U.S. Pat. No. 5,648,727. The capacitive sensor senses a level of the fluid and determines that level in relation to a known "home" position. The tube 20 is placed in a holding device (see FIG. 4) so that a bottom of the tube 20 is at the reference line "X" which is used as a reference point for discussion purposes only.

5. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Yu US 5,779,907.

Yu discloses an apparatus for immunoassay using a 96-well microplate includes a mechanism for supporting the microplate in a relatively fixed position, a magnetic microplate assembly containing multiple cylindrical magnets positioned in 4X6 arrays for insertion from the bottom of the microplate in the spaces between the wells of the microplate, and a device for moving the magnet microplate assembly relative to the microplate thereby to permit selective separation of magnetic components within the microplate wells. The magnets, preferably cylindrical in configuration, are placed between groups of four wells in the microplate. The magnetic microplate assembly is reusable. The magnets do not come into contact with any of the fluids within the wells of the microplate.

A reusable magnet microplate assembly 20 is shown in FIG. 1 positioned below the microplate 10. The plate assembly 20 includes a support plate 22 on which is mounted a plurality of individual **magnets 24**. In the preferred embodiment of this invention, there is one magnet 24 for each group 16 of four wells. Thus, for a ninety-six well microplate, the magnet microplate assembly will include twenty-four magnets 24. While a ninety-six well microplate is illustrated, this invention is equally applicable to standard 6, 12, 24, 48 tissue culture plates.

A microplate 10 is secured to a shaker table 50, and the magnet microplate assembly 20 is attached to an elevator mechanism 55 (magnet moving means), which comprises means for moving the magnet microplate assembly relative to the microplate thereby to permit selective separation of magnetic components within the wells of the microplate. **A conventional liquid insertion and removal assembly 60** (suction

nozzle) is attached to an elevator 65. From time to time during the process, the assembly 60 is lowered to place pairs of hollow needles 68 into individual wells.

A principal advantage of the invention is that a single, disposable microplate is used throughout an immunomagnetic separation process without unnecessary handling by an operator. Sample dilution, incubation, soaking, orbital shaking, magnetic separation, bead wash, rinse and reagent **dispensing in the magnetic separator may be accomplished automatically under computer program control.**

6. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilks US 5,578,495.

Wilks discloses a solids preparation and extraction device. This device can be independently mounted in an appropriate housing in the combination subsequently described and employed to process only solid or semi-solids materials delivered on station thereto via a feed tray, magazine or carrousel. Alternatively, this device can be mounted in an appropriate housing with the additional sub-components (B) and (C), supra, to provide an instrument suitable for handling, on the same feed tray, magazine, or carrousel, vials, or bottles, which contain both (i) fluid samples and (ii) solid or semi-solids samples from which organic fluid or solids specimens can be extracted.

The instrument employed to extract and recover the organic liquid or solids components from a given amount of a solid or semi-solids material, and inject said recovered components to an analytical unit, include a solids preparation and extraction sub-assembly 200, a syringe 10 (suction nozzle), and a carrousel feed tray 50. All are contained within a suitable housing. The feed tray 50 transports in programmed

sequence the bottles 250, containing weighed amounts of the solids or semi-solids samples, to a position for operation thereon by the solids preparation and extraction assembly 200. The carrousel feed tray 50 provides seating locations for the bottles, or vials, in any programmed order as desired for analysis. The circumferential edges of the upper sample tray holder 52 and tray base 54 of the carrousel feed tray 50 within which the bottles or vials are placed are slotted, or cut away providing slots 5 which permit ready access for lifting the vials for processing, and extraction of components for analysis.

The solids preparation and extraction sub-assembly 200, as shown by any of FIGS. 1-4, includes generally an electrical heater, or oven 210, and an elevator assembly 220 inclusive of an upper carriage section 222_2 and a lower carriage section 222_1. It further includes an elevator motor 221 for raising and lowering the elevator assembly 220 (magnet moving means), and a stir motor 223 (magnet) for inductive rotation of the magnetic stir bar 258 contained within vial 250.

7. Claim 3 is rejected under 35 U.S.C. 102(e) as being anticipated by Schultz et al. US 6,033,911.

Schultz et al. discloses an automated assaying system is disclosed having a multiplicity of lumens oriented and controllable in clusters. The lumens are portrayed in a matrix, wherein each row of the matrix consists of one such cluster that is individually controllable for aspiration and dispensation purposes. Also provided is a unique wash system capable of flushing the entirety of the system. A method is also depicted for accomplishing this unique assaying.

The device a hydraulic solution source 50 which may contain any acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, a pump 12 (liquid conveying means) is thereafter connected thereto. Pump 12 is preferably of the peristaltic type, however, any fluid-type pump may be employed. From pump 12, a conduit 14 consisting of branch tubing coupled to, in this case, as depicted, two valves 16. The distribution valves 16 channel the wash fluid into a plurality of controllable cells 32. For example, as depicted, the distribution valves 16 provide output lines as arterial tubing 18 in equal numbers of six which spread to 12 of the housings 32 (manifold) via a valve 30 on each housing 32.

Syringes 52 (suction pump), of course, contain plungers 54 on plunger shafts 82. As there are eight syringes depicted in FIGS. 3 and 4, with four being to the front of the unit and four being to the rear, a plunger-pushing base 62 couples all of the syringe plunger shafts 82 together in any given unit. A motor 72, also coupled to a computer system, may specifically meter volumes via the syringes 52, either positively or negatively. That is, the plungers 54 may be pushed up to force fluid out of the system, or the plungers 54 may be drawn down to suction fluid into the system, both through probes 26 (suction nozzles).

As can be seen in FIGS. 4 through 6, the top spider ports 64 and the bottom spider ports 66 are slightly offset. This slight offset allows for the 180 degree rotation of an internal shaft 80 which acts as a valve key sleeve within an outer sleeve 78. That valve key sleeve 80, as depicted in FIGS. 5 and 6, contains, importantly, two grooves 74. While in an open position, those grooves orient with the spider ports 56. However,

when those grooves 74 are rotated 180 degrees, they no longer align with the spider ports 56, but instead a solid portion of the key sleeve 80 orients with those ports, closing them off from the wash system downstream. Therefore, when in a closed position, the system is controllable only by syringes 52 via motors 72, but not by pump 12. Importantly, each motor 72 may be individually controlled. Therefore, as depicted in FIG. 1, each of the twelve syringe housings 32, containing eight syringes and output ports, are individually controllable via a motor 72.

Thereafter, the lumens 34 extending from tips 60 are arranged as ganged clusters within tubing management housing 20. Tubing management housing 20 is preferably a flexible tract housing. Oriented with tubing management housing 20 is a swivel 48. Swivel 48 allows the upper portion of the tubing management housing 20 to slightly disorient or skew itself without binding of the lumens contained therein. That is, as tubing management housing 20 is moved about, swivel 48 allows that portion of tubing management housing 20 above swivel 48 to swivel freely so as not to foul. Tubing management housing 20 is also coupled to a three-dimensional robotic arm system (suction nozzle moving means), consisting of a vertical motion shaft 36, lateral motion couple 38 and longitudinal motion sleeve 40. The vertical motion shaft 36 is coupled at an upper portion to the management tubing 20, slightly below the swivel 48, and then at a lower portion to a U-shaped bracket 46 (support means).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. as applied to claim 3 above, and further in view of Tyberg and Yu.

Schultz does not teach a device that comprises nozzle moving including urging means for urging the suction nozzles toward the vessel, magnet, and a magnet moving means.

Tyberg discloses a pipetting station 24 (moving means) includes the pipetting arm 32 (support means) that moves in the direction of arrow 42, and a pipetting probe 34 **spring** (urging means) mounted to the pipetting arm 32 of the pipetting station 24. The pipetting probe 34 includes a pipetting tip 36 having a capacitive level sensor as described with reference to U.S. Pat. No. 5,648,727. The capacitive sensor senses a level of the fluid and determines that level in relation to a known "home" position. The tube 20 is placed in a holding device (see FIG. 4) so that a bottom of the tube 20 is at the reference line "X" which is used as a reference point for discussion purposes only.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Schultz et al. by employing the sensing system of Tyberg in order to prevent the probes 26 of the device of Schultz from breaking in the event that the robotic system moves the probes down to far to contact the basin 28.

Yu discloses microplate 10 is secured to a shaker table 50, and the magnet microplate assembly 20 is attached to an elevator mechanism 55 (magnet moving means), which comprises means for moving the magnet microplate assembly relative to the microplate thereby to permit selective separation of magnetic components within the wells of the microplate. **A conventional liquid insertion and removal ass mbly 60** (suction nozzle) is attached to an elevator 65. From time to time during

the process, the assembly 60 is lowered to place pairs of hollow needles 68 into individual wells.

A principal advantage of the invention is that a single, disposable microplate is used throughout an immunomagnetic separation process without unnecessary handling by an operator. Sample dilution, incubation, soaking, orbital shaking, magnetic separation, bead wash, rinse and reagent **dispensing in the magnetic separator may be accomplished automatically under computer program control**.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the modified device of Schultz et al. by incorporating the magnetic system of Yu to allow for stirring of the assay materials deposited in the wells of the basin.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Little et al., Bienert et al., Wilmes et al., Overbeck et al., Komatsu et al., Fawcett et al., Fukunaga, Tajima (,631), Koike, Chow et al., and Settler discloses aspiration and dispensing systems.

Astle, Rutishauser et al., Hayashi, and Matte et al. disclose magnetic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is (703) 305-0399. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

brg
August 8, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700